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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------|------------------|
| 09/361,425 | 07/27/1999 | JOHN KUNG | JBP461 | 5503 |
| 7590 04/06/2004 PHILIP S. JOHNSON, ESQ. JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | EXAMINER KAM, CHIH MIN | |
| | | | ART UNIT 1653 | PAPER NUMBER |

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/361,425 | KUNG ET AL. | |
| | Examiner | Art Unit | |
| | Chih-Min Kam | 1653 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7, 14, 16-19 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 16 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17, 19 and 22-24 is/are allowed.
- 6) ☒ Claim(s) 7, 21 and 25 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The Request for Continued Examination (RCE) filed January 22, 2004 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 7, 14, 16-19 and 21-25 are pending.

Applicants' amendment filed on January 22, 2004 is acknowledged, and applicants' response has been fully considered. Claims 7, 17, 19 and 22-24 have been amended, claim 20 has been cancelled, and a new claim 25 has been added. Claims 14 and 16 are non-elected invention, thus withdrawn from consideration. Therefore, claims 7, 14, 16-19 and 21-25 are examined. Regarding rejoining the product and process claims, please see the following paragraphs:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

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examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Objection Withdrawn

Claim Objections

3. The previous objection of claim 22 is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 5 in the amendment filed January 22, 2004.

Rejection Withdrawn

Claim Rejections - 35 USC § 102

4. The previous rejection of claims 7 and 17-24 under 35 U.S.C.102(a), as being anticipated by Jiang *et al.* (J. Nutritional Biochemistry 9, 362-369 (July 1998)), is withdrawn in view of

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applicants' amendment of the claims, applicants' cancellation of the claim and applicants' response at page 6 in the amendment filed January 22, 2004.

5. The previous rejection of claim 20 under 35 U.S.C.102(a), as being anticipated by Fisher *et al.* (WO 98/55075), is withdrawn in view of applicants' cancellation of the claim in the amendment filed January 22, 2004.

Claim Objections

6. Claims 18 and 21 are objected to because of the use of the term "A composition according to claim 7". Since the claim is dependent from claim 7, the term "The composition according to claim 7" is suggested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent; or,
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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7. Claims 7, 21 and 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Fisher *et al.* (WO 98/55075).

Fisher *et al.* teach a composition for inhibiting subMED UV-induction of MMP in human skin comprising an effective amount of at least one ingredient selected from the group consisting of a retinoid, N-acetylcysteine, vitamin C (ascorbic acid) and mixtures thereof, where the composition can be a lotion or cream and applied to the skin (claims 18, 23 and 28 of WO 98/55075; page 5, lines 1-4; page 15, line 27-page 16, line 32), which meets the criteria of claims 7, 21 and 25.

In response, applicants indicate claim 7 has been amended to indicate N-acetylcysteine should be present in a “stabilizing effective amount”; and Fisher *et al.* only indicate retinoids, ascorbic acid and N-acetylcysteine as potential MMP inhibitors for human skin, it does not propose the composition of the presently amended claims, wherein an amount of N-acetylcysteine is effective to stabilize the oxygen-labile species (pages 6-7 of the response). The argument is not persuasive because the reference indicates various compounds termed “antioxidants” are useful as MMP inhibitors (page 15, line 27), and an effective amount of N-acetylcysteine is included in the composition, thus N-acetylcysteine would be expected to stabilize other oxygen-labile species because of the property of the compound.

8. Claims 7, 21 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Fisher *et al.* (U. S. Patent 6,130,254).

Fisher *et al.* teach a composition for inhibiting subMED UV-induction of MMP in human skin comprising an effective amount of at least one ingredient selected from the group consisting of a retinoid, N-acetylcysteine, vitamin C (ascorbic acid) and mixtures thereof, where the

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composition can be a lotion or cream and applied to the skin (claims 8 and 13 of the patent; column 11, line 26-column 12, line 14), which meets the criteria of claims 7, 21 and 25.

9. Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

7. Claims 7, 21 and 25 are rejected, and claim 18 is objected. It appears that claims 17, 19 and 22-24 are free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

March 30, 2004